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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER -

1647

DATE MAILED: 04/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,704

Applicant(s)

VICKERS ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of species human growth hormone reading on claims 1-12, in Paper No. 11 (7 February 2003) is acknowledged. Applicant did not distinctly and specifically point out any errors in the species election requirement or traverse the species election requirement. Claims 1-12 are pending.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Drawings

4. The drawings have been approved by the draftsman.

Claim Objections

5. Claims 2, 7 and 12 are objected to because of the following informalities:

(i) Claims 2 and 7 contain inappropriate punctuation. For example, they contain commas that are misplaced.

(ii) Claim 12 has a period in the middle of a sentence.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 1, 2, 7 and 10 recite broadly the term "...an agent...". It is unclear what these agents are. Therefore, the metes and bounds of the claim are unclear. Claims 3-6 are rejected insofar as they depend on claim 1.

5b. Claims 2, 8 and 10 are rejected for reciting the terms "analog thereof or a functionally equivalent ligand" because the terms are vague and indefinite and are not defined in the specification. It is not clear what is implied by "analog thereof or a functionally equivalent ligand" of an agent. Specification has described agents that act as agonists on the growth hormone receptor; however, it's unclear what the functional capabilities of the analogs and the functionally equivalent ligand. Therefore, the metes and bounds of this claim are unclear. Claims 9-12 are rejected insofar as they depend on claim 8.

5c. Claim 7 is indefinite because the claim recites the "...an anti-hypertensive agent...". It is unclear what these anti-hypertensive agents are. Therefore, the metes and bounds of the claim are unclear.

5d. Claim 8 is incomplete because it fails to achieve the goal set forth in the preamble of the claim. Claims 9-12 are rejected insofar as they depend on claim 8.

5e. Claim 8 rejected for reciting the term "effective concentration" because the term is vague and indefinite and is not defined in the specification. It is not clear what is implied by "effective concentration" of growth hormone, an analog thereof etc. Therefore, the

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metes and bounds of this claim are unclear. Claims 9-12 are rejected insofar as they depend on claim 8.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8a. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (1994) in view of both Job et al. (1996) and Coves et al. (1989).

The instant invention is directed to a method of treating hypertension in a mammal with intrauterine growth retardation (GH) by administering growth hormone.

Baker et al. (1994) teaches that babies who are small at birth and during infancy are known to be at an increased risk of developing coronary heart disease, hypertension and diabetes during adult life (abstract). It is suggested that these

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diseases are 'programmed' by an inadequate supply of nutrients or oxygen in utero or immediately after birth. It is argued that in men, weight at 1 year, that is growth in infancy, is a stronger predictor of coronary heart disease than birth weight (page: 225). From adults who are still living they conclude that babies who were small have, as adults, raised blood pressure (page: 225). In addition, it is indicated that systolic pressure falls away progressively between those who were small at birth and those who were large (page: 225). This implicates impaired fetal growth and birth weight with higher blood pressure. However, Baker et al. do not explicitly recite the administration of GH to treat hypertension in a mammal, which has experienced intrauterine under nutrition and/or growth retardation or an adverse postnatal environment.

The Job et al. (1996) reference teaches the administration of GH to treat severe growth retardation of intrauterine onset. This study demonstrates a GH dose-dependent effect on growth acceleration in persistent postnatal severe growth retardation of intrauterine onset (abstract). Further, it is indicated that the clinical and biological tolerance of treatment was good (abstract). Although, Job et al. administer GH to patients it is not for the purpose of treating growth retardation and not hypertension.

Coves et al. (1989) is relied upon to demonstrate the effect of GH hormone on both systolic and diastolic pressure (page: 293, table 1). In this study it has been shown that patients with non-insulin-dependent diabetes mellitus (NIDD) and essential hypertension were treated with Guanfacine that elevated the GH in the plasma along with the reduction of blood pressure.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat hypertension in a mammal with intrauterine growth retardation (GH) by administering growth hormone to said mammals because Baker et al. describes that babies that show growth retardation develop hypertension in adult life; Job et al. teaches the administration of GH to treat severe growth retardation of intrauterine onset; Coves et al. teaches the effect of GH on blood pressure of patients with hypertension. One of ordinary skill in the art would have been motivated to use GH to treat patients with hypertension who experienced intrauterine growth retardation. Thus the claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary. Therefore, the instant invention is obvious over Baker et al. (1994) in view of both Job et al. (1996) and Coves et al. (1989).

9. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
April 21, 2003



LORRAINE SPECTOR
PRIMARY EXAMINER